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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,908	11/03/1998	OREST W. BLASCHUK	100086.409.	1195

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/185,908	BLASCHUK ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/11/03 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-20,27-43,46-49,52-55 and 58-61 is/are pending in the application.

4a) Of the above claim(s) 7-20,33,34,38-43,46-49,52-55 and 58-61 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-6, 27-32 and 35-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 07/11/2003, is acknowledged.

3. Claims 2-20, 27-43, 46-49, 52-55 and 58-61 are pending.

4. Claims 7-20, 33-34, 38-43, 46-49, 52-55 and 58-61 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

5. Claims 2-6, 27-32 and 35-37 are under consideration in the instant application.

6. In view of the amendment filed on 07/11/2003, only the following rejection remained.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-6, 27-32 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims recite any cell adhesion modulating agent that comprises at least five consecutive amino acid residues of any claudin CAR sequence, said claudin CAR sequence being present in a naturally occurring claudin and having the formula of SEQ ID NO:1, and contains no more than 50 consecutive amino acid residues. Such recitation does not limit the cell adhesion modulating agent to an amino acid between 1-50 consecutive amino acid residues comprising SEQ ID NO:1, but rather any amino acid sequence between 1-50 of any claudin CAR sequence. The claims read on agent that does not have to have SEQ ID NO:1. Indeed the naturally occurring claudin CAR would comprise SEQ ID NO:1, but the agent is not limited to comprise SEQ ID NO:1, but any part of a claudin CAR sequence thereof.

Claim 27 recites the agent is linked to a drug while claims 35-37 recite a pharmaceutical composition, however it is unclear whether or not the claimed composition would function as pharmaceutical composition. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the

claimed pharmaceutical composition are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Further, the terms "comprises" and "having" are open-ended, they open up the formula of SEQ ID NO: 1 to include additional unrecited amino acid residues at N- or C- or both termini of SEQ ID NO:1. . Furthermore, the applicant's disclosure has not provided sufficient guidance or specific examples for the skilled artisan to determine the at least 45 unknown amino acids. It is recognized in the prior art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence and the functional properties of the different parts of the protein. For example, Wierzbicka-Patynowski et al, in J Biol. Chem. (274(53):37809-37814, 1999) teach that structural requirements of echistatin for the recognition of $\alpha v\beta 3$ and $\alpha 5\beta 1$ integrins. Wierzbicka-Patynowski et al, further teach that methionine, aspartic acid C-terminal in the RGD sequence and the HKGPAT motif at the C-terminus contribute to the selective recognition of integrin receptors (see page 37813 last paragraph in particular). The claims as written encompass a broad genus of polypeptides with an unlimited number of possibilities with regard to the at least 45 amino acids out of 50 amino acid residues. Further, an assay for finding a product is not equivalent to a positive recitation of how to make a product.

There is insufficient guidance in the specification to allow the skilled artisan to determine which 5 or 7 consecutive amino acids of SEQ ID NO: 1 would modulate the cell adhesion, specially because SEQ ID NO:1 represents a consensus of conserved functional domain.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant submits that an artisan of ordinary skill in view of the instant disclosure, could readily identify, make and use naturally occurring claudin CAR sequences according to the claimed invention, including claudin CAR sequences other than numerous naturally occurring claudin CAR sequences specifically recited by the specification. Applicant argues that a simple sequence search of publicly available databases using a claudin-1 CAR query sequence according to the instant disclosure readily identifies numerous naturally occurring claudin car sequences meeting the definition of Applicants' SEQ ID NO:1.

However, none of the illustrated naturally occurring Claudin CAR sequences of SEQ ID NO:1 has been show to modulate cell adhesion and all the Claudin CAR sequences disclosed in the search comprises more than 50 amino acids sequence in length. While applicant argues that such Claudin CAR sequences of SEQ ID NO:1 are expected to modulate cell adhesion. However, the disclosed claudin CAR sequences are disclosed as a full length protein which contain more than 50 amino acids sequence which of none has been shown to mediate cell adhesion.

Applicant provides a homology studies to the present claudin CAR sequences of SEQ ID NO:1 in the patented literature to establish that a patent applicant need not teach, and preferably omits, what is well known in the art. However, the Examiner cannot comment on the issued patent. Further, patentability is determined on the totality of the record, by a preponderance of the evidence with due consideration to persuasiveness of argument.

Applicant submits that the disclosure, coupled with the general level of knowledge and understanding in the art of cell adhesion proteins, provides the skilled artisan of cell adhesion proteins, provides the skilled artisan with a more than reasonable expectation that a five amino acid sequence of SEQ ID NO:1, as currently claimed can be used as a cell modulating agent. However, The specification does not provide sufficient guidance to allow the skilled artisan to determine which five amino acids sequence of SEQ ID NO:1 would modulate cell adhesion since SEQ ID NO:1 represents a consensus sequence with a conserved functional domain.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
September 8, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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